

AMENDMENTS TO THE CLAIMS

1. (Original) A composition comprising at least one insoluble active substance together with at least one wetting agent, wherein the concentration of said wetting agent is sufficient to form a stable, flocculated suspension of said active substance, wherein said composition contains substantially no polyethylene glycol, propylene glycol, sorbitol or glycerol.

2. (Original) The composition of claim 1, wherein said active substance is megestrol acetate and said wetting agent is at least one member selected from the group consisting of nonionic, cationic, anionic, and zwitterionic surfactants.

3. (Original) The composition of claim 1, wherein the concentration of said wetting agent is within the range of about 0.0001% to about 1.5% w/w.

4. (Original) The composition of claim 1, wherein the concentration of said wetting agent is within the range of about 0.0005% to about 1% w/w.

5. (Original) The composition of claim 1, wherein the concentration of said active substance is within the range of about 0.1% to about 25% w/v.

6. (Original) The composition of claim 1, wherein the concentration of said active substance is within the range of about 1 to about 10% w/v.

7. (Original) The composition of claim 1, wherein the concentration of said active substance is about 4% w/v.

8. (Original) The composition of claim 1, further comprising at least one suspending agent.

9. (Original) The composition of claim 8, wherein said suspending agent is present at a concentration within the range of about 0.01 to about 1.0% w/w.

10. (Original) The composition of claim 8, wherein said suspending agent is present at a concentration of within the range of about 0.1% to about 0.3% w/w.

11. (Original) The composition of claim 8, wherein said suspending agent is at least one hydrocolloid material.

12. (Original) The composition of claim 11, wherein said hydrocolloid material is at least one member selected from the group consisting of pharmaceutically acceptable gums.

13. (Original) The composition of claim 1, wherein said composition comprises at least two wetting agents.

14. (Original) The composition of claim 1, wherein said wetting agent is at least one member selected from the group consisting of docusate sodium and ethylene oxide/propylene oxide copolymers and block copolymers.

15. (Currently Amended) The composition of claim 14, wherein the concentration of said wetting agent[[s]] is within the range of about 0.0001 to about 0.04%.

16. (Original) The composition of claim 15, wherein the concentration of said wetting agents is within the range of about 0.001 to about 0.02%.

17. (Original) The composition of claim 13, wherein said composition further comprises at least one suspending agent.

18. (Original) A method for forming an aqueous flocculated suspension containing an insoluble micronized active substance together with a wetting agent to form a stable, resuspendable flocculated suspension of said active substance, which comprises adding said wetting agent in an amount below which the floccule size of said active

substance in said suspension starts to increase, wherein substantially no polyethylene glycol, propylene glycol, sorbitol or glycerol is included in said suspension.

19. (Original) The method of claim 18, wherein said active substance is megestrol acetate.

20. (Original) The method of claim 18, wherein said wetting agent is docusate sodium.

21. (Original) The method of claim 20, which comprises adding said docusate sodium in an amount of about 0.001 to about 0.03% w/w.

22. (Original) The method of claim 20, which comprises adding said docusate sodium in an amount of about 0.005% to about 0.01% w/w.

23. (Original) The method of claim 18, wherein said flocculated suspension comprises floccules having a mean floc size diameter of at least about 12 microns.

24. (Original) The method of claim 18, wherein said flocculated suspension comprises floccules having a mean floc size diameter of about 12 to about 50 microns.

25. (Original) The method of claim 18, wherein said flocculated suspension comprises floccules having a mean floc size diameter of about 23 to about 40 microns.

26. (Original) An oral pharmaceutical composition, comprising:

a) about 0.5 to about 10% w/v of megestrol acetate;

b) about 0.001 to about 2% w/w of at least one wetting agent selected from the group consisting of docusate sodium and ethylene oxide/propylene oxide copolymers and block copolymers; and

c) about 0.05 to about 0.5% w/w of at least one suspending agent, wherein said composition contains substantially no polyethylene glycol, propylene glycol, sorbitol or glycerol.

27. (Original) The composition of claim 26, comprising about 0.005 to about 0.04% w/w of docusate sodium.

28. (Original) The composition of claim 26, wherein said suspending agent is a pharmaceutical grade gum.

29. (Original) The composition of claim 27, comprising about 0.005 to about 0.02% w/w of docusate sodium.

30. (Original) The composition of claim 27, comprising about 0.005 to about 0.02% of at least one member selected from the group of ethylene oxide propylene oxide copolymers and block copolymers.

31. (Original) The composition of claim 30, wherein said suspending agent is present in said composition in an amount of from about 0.1 to about 0.3% w/w.

32. (Original) The composition of claim 29, wherein said composition contains floccules having a mean floc size diameter of at least about 12 microns.

33. (Original) The composition of claim 32, wherein said composition contains floccules having a mean floc size diameter of at least about 21 microns.

34. (Original) An oral composition, comprising about 1 to about 8% w/v of megestrol acetate, wetting agents consisting essentially of about 0.005 to about 1% w/w of docusate sodium and about 0.005 to about 1% w/w of at least one ethylene oxide propylene oxide copolymer; and further comprising from about 0.1 to about 0.3% w/w of at least one hydrocolloid material.

35. (Original) The composition of claim 34, wherein said composition is in the form of an aqueous flocculated suspension which is storage stable for at least about 3 months.

36. (Original) The composition of claim 34, wherein said composition is storage stable for at least about 12 months.

37. (Original) The composition of claim 34, said composition containing substantially no polyethylene glycol.

38. (Original) The composition of claim 34, said composition containing substantially no propylene glycol, glycerol or sorbitol.

39. (Original) A method of forming an oral pharmaceutical composition, comprising:

combining a first portion of a pharmaceutical grade gum and water in a first vessel;

combining a second portion of megestrol acetate and at least one wetting agent in a second vessel;

combining the contents of said first vessel with the contents of said second vessel, wherein said wetting agent is at least one member selected from the group consisting of docusate sodium and ethylene oxide/propylene oxide copolymers and block copolymers, and further wherein said composition contains substantially no polyethylene glycol, propylene glycol, sorbitol or glycerol.

40. (Original) A method of forming an oral pharmaceutical composition, comprising:

admixing megestrol acetate and at least one wetting agent, said wetting agent consisting essentially of at least one member selected from the group of docusate

sodium and ethylene oxide/propylene oxide copolymers, wherein said composition contains substantially no polyethylene glycol, propylene glycol, sorbitol or glycerol.

41. (Original) The composition of claim 1, wherein said wetting agent is within the range of about 0.001 to about 0.05% w/w.

42. (Original) An oral composition, comprising about 1 to about 8% w/v of megestrol acetate, a wetting agent consisting essentially of docusate sodium; and further comprising from about 0.1 to about 0.3% w/w of at least one hydrocolloid material.

43. (Original) An oral composition, comprising about 1 to about 8% w/v of megestrol acetate, a wetting agent consisting essentially of an ethylene oxide/propylene oxide block copolymer; and further comprising from about 0.1 to about 0.3% w/w of at least one hydrocolloid material.

44. (Currently Amended) The composition of claim 43, wherein said block copolymer [is PLURONIC F 127] has an average molecular weight of about 12600 and comprises ethylene oxide and propylene oxide in a ratio of about 2.7:3.0 by molecular weight.

45. (Original) The composition of claim 1, further comprising an anti-foaming agent.

46. (Original) The composition of claim 26, further comprising an anti-foaming agent.